Holes on sutures

Measures based on a study.

Out on the nerve cuff (exiting nerve) to maintain wrapped around. (wrap around exiting nerve tissue 360 degrees, and suture or weld).

Slit goes around inglinal canal areas. As tacking sutures around the canal floor, the inglinal chord (tails are overlapped and surtured around chord.) may take flat piece of mesh and warp around a cone. The diameters shoud be gibber.

Also around artery or vein exiting from the heart. cardiac vessile. ((no perferations in spinal appn)). All of these are preferred to be non-porous.

Film with 25 microns for fluid but not cell passage. (fluid to come through for). Laminectomy (usu with more fusion procedures). would be bone regeneration macrous membrane. ((ex. Could cover dura and exiting nerve roots with anti adhesion film and then lay down macroporous membrane to support the muscle. Alternatively, could do nonporous support membrane.

At upper end of the ((ex. Surger from L3 to L5, prob remove the spinal processes, drape adhesive under dura in upper and distal lower part of canal).

Over exiting never roots. Laminotomy. procedures which are smaller. Microdisectimy. Dura can be exposed with exiting nerve roots. ADHESIVE IS APPLIED TO THE DURA. ((Placed onto dura, which is a layer of nerves. Generally dura is not damaged but may be penetrated. not nerve tissue.) ((Foramen is the bigger hole. Also the exiting nerve root (can find osteophytes (bony outcrops) or injured nerves or disk tissue. of bone that can compress nerve, may also have protruding disk into foramen.

33.

a. wherein a thickness of the layer of resorbable polymer base material, measured between the first substantially-smooth side and the second substantially-smooth side, is between about 10 microns and about 300 microns;

wherein the layer of resorbable polymer base material is adapted to maintain a smooth-surfaced barrier between the healing trauma site and the adjacent surrounding tissue for a relatively extended period of time sufficient to attenuate or eliminate any formation of scar tissue between the trauma site and the adjacent surrounding tissue, and is adapted to be resorbed into the mammalian body within a period of approximately 18 to 24 months from an initial implantation of the implant into the mammalian body.

34. The resorbable scar-tissue reduction micro-membrane set forth in Claim 12, wherein a slit is formed in a periphery of the resorbable scar-tissue reduction micro-membrane so that the edge extends along the slit.

35. A method of preventing fibrotic adhesion at a surgical site, comprising:

a. covering the surgical site with a membrane material as in claim 1.

36. The method of claim 9, further including attaching the membrane material to the surgical site.

37. The method of claim 10, wherein the step of attaching comprises suturing.

38. The method of claim 10, wherein the step of attaching comprises adhering with a fibrin sealant.

39. The method of claim 10, wherein the step of attaching comprises heat sealing.

40. The method of claim 13, wherein the heat sealing is accomplished at multiple locations using a bipolar electro-cautery device.

The method of claim 14, further including supplementing the heat sealing with an alternative means of attachment.

Additionally, the prior art cell-occlusive, fluid-permeable membrane 10 is non-resorbable, and cannot be absorbed by the patient's body. Consequently, in order to avoid the risk of bacterial infection, the cell-occlusive, fluid-permeable membrane 10 must be removed during a subsequent operation, which may introduce further complications and risks to the patient. Thus, in addition to being cell-occlusive, prior membranes suffer from lack of inherent strength and non-resorbability.

The implant is adapted for protecting the bone defect from a prolapse of adjacent soft tissues into the bone defect during repair of the bone defect and, further, is adapted for preventing stress shielded resorption of bone after the repair of the bone defect. The bone, which is prevented from being resorbed, may include either an autograft, an allograft, and/or new regenerated bone within the bone defect.

The fixation device may be resorbable or non-resorbable. When the fixation device is resorbable, the fixation device loses its mechanical strength within 24 months and, more preferably, within 4 to 12 months. This loss of mechanical strength of the fixation device can prevent resorption of new bone near the bone defect which would occur if the bone defect were stress shielded by either the fixation device, the implant, or both. If the fixation device is non-resorbable, according to the present invention, the resorption of the implant can reduce stress shielding of the bone defect area to thereby minimize resorption of new bone near the bone defect. As another option, the implant may be non-resorbable, but flexible enough to prevent stress shielding of the bone defect after the resorbable fixation device has lost its mechanical strength.

The resorbable membrane forms a tube surrounding the entire bone defect area and overlapping the adjacent areas of bone near the bone defect area, when the resorbable membrane is secured both around the bone defect area and to the adjacent areas of bone near the bone defect area. The resorbable membrane can be frictionally secured around the bone defect area, or can be secured around the bone defect area using at least one of clamps, staples, screws, sutures, and tacks. The fixation device can include at least one of a plate, a screw, an intramedullary rod, and an external fixation device.

According to yet another aspect of the present invention, a method of protecting a biological tissue defect area from soft tissue interposition is provided. The method includes a step of placing a resorbable membrane outside of a boundary of the biological tissue defect, where the resorbable membrane comprises a plurality of apertures adapted for allowing a proliferation of vasculature and connective tissue cells therethrough, while preventing the prolapse of adjacent soft tissues into the biological tissue defect. The biological tissue defect area can include a bone defect area, and the step of placing a resorbable membrane outside of the boundary of the bone defect area can include a step of wrapping the resorbable membrane around two ends of a long bone to thereby surround a void between the two ends of the long bone. A rigid fixation device can subsequently be secured between the two ends of the long bone.

The protective bone regeneration membrane 42 of the presently preferred embodiment is preferably resorbed within the body of the patient to a point where substantial mechanical fixation is no longer exerted on the first section 75 and the second section 77 of the long bone 68, within a period of approximately 1 year. Complete resorption of the protective bone regeneration membrane 42 may subsequently occur after a total period of 11/2 to 2 years have elapsed since the initial implantation.

Cautery unit, mftd gy Valley Lab.

Notched membrane in sterile packaging. (notch fits in recess of sinus process & could weld there).

Tabbed membrane in sterile packaging. Tabs allow you to tuck.

Pref'd embod: Weld to bone at yellow lines & each end.

A process referred to as guided tissue regeneration is widely used by periodontists to regenerate bone and periodontal ligaments (ligaments between the tooth root and the bone) around dental implants, for example. This surgical procedure uses cell-occlusive (cells cannot pass through) but fluid-permeable membranes, which are otherwise known as semipermeable membranes, in order to cover and segregate a bone defect from the surrounding soft tissues. U.S. Pat. No. 3,962,153 discloses such a cell-occlusive, fluid-permeable membrane. Use of these cell-occlusive, fluid permeable membranes, has been predominantly developed and used by periodontists over the last decade, who worked in the mouth around teeth. The human body has many tissue types which originate from three primary germ layers of the embryo: the ectoderm, the mesoderm and the entoderm. From the ectoderm are derived the skin and its attached tissues, such as nails, hair and glands of the skin, the nervous system, external sense organs and the epithelial lining of the mouth and anus. From the mesoderm are derived the connective tissues, bone, cartilage, muscle, blood and blood vessels. From the entoderm are derived, among others, the digestive tract, bladder and urethra. The "precursor" cells of these layers are limited to only becoming cells of their respective tissue type. Bone, muscle, connective tissue, blood vessels and cartilage are of mesenchymal origin which means from the meshwork of embryonic connective tissue in the mesoderm, and are formed from versatile mesenchymal stem cells, whereas the lining of the mouth is of ectodermal origin and is formed of epithelial cells derived from the ectoderm. Ectodermal cells do not have the potential to become bone forming cells and, conversely, mesenchymal cells do not have the potential to form epithelium.

Epithelial cells are present in the mouth, but are not present in many other areas of the mammalian skeletal system, such as areas near long bones of the mammalian skeleton. The development of cell-occlusive, fluid permeable membranes was developed in the context of periodontal and oral applications, for the purpose of excluding the introduction of epithelial cells into the bone defect area of the patient because they are believed to hinder bone formation. Epithelial cells proliferate faster than bone cells and, therefore, the exclusion of these epithelial cells from the bone defect area has been considered to be essential for optimal bone and ligament regeneration in these periodontal and oral applications. Although cell-occlusive, fluid permeable membranes have been predominantly used in periodontal and oral applications, these cell-occlusive membranes have recently also been applied for tissue segregation in other defect sites in the mammalian skeletal system, such as long bone defects.

In addition to being cell-occlusive, the cell-occlusive, fluid permeable membrane 10 suffers from a lack of rigidity, as evidenced by the hour-glass configuration of the cell-occlusive, fluid-permeable membrane 10 in FIG. 1. A typical thickness of the cell-occlusive, fluid-permeable membrane 10 comprises less than 5 microns. Since periodontal defects are typically small, and since oral soft tissues typically do not apply much pressure, the cell-occlusive, fluid-permeable membrane 10 of the prior art has maintained its very thin and flexible configuration. Unfortunately, this very thin and flexible configuration, which is somewhat suitable for periodontal and oral applications,

is not suitable for maintaining and protecting a sufficiently large bone defect area 20 in non-periodontal and non-oral applications. Since muscles are much larger and more powerful in orthopedic applications, for example, the cell-occlusive, fluid-permeable membrane 10 cannot provide sufficient protection against the prolapse of soft tissues into the bone defect area 20. When the surrounding tissues prolapse into the bone defect area 20, these interposed tissues present a physical barrier for the regenerating bone. The regenerating bone will not be able to push the interposed soft tissues out of the bone defect area, and subsequently, further regeneration of the bone in these areas occupied by the prolapsed soft tissues is prevented. A "non-union" (or pseudoarthrosis which means pseudo-joint) may result, comprising fibrous scar tissue instead of bone. Additionally, the prior art cell-occlusive, fluid-permeable membrane 10 is non-resorbable, and cannot be absorbed by the patient's body. Consequently, in order to avoid the risk of bacterial infection, the cell-occlusive, fluid-permeable membrane 10 must be removed during a subsequent operation, which may introduce further complications and risks to the patient. Thus, in addition to being cell-occlusive, prior membranes suffer from lack of inherent strength and non-resorbability.

The fixation device is secured onto the bone of the patient with the screws and is designed to be permanently left inside the patient. Any proliferation of blood vessels through these screw holes would be destroyed by any subsequent removal of the fixation device. On the other hand, if the fixation device is left in permanently, which is a disclosed embodiment, the bone of the patient will be permanently stress shielded. In other words, the mended bone, after initial healing will subsequently start to resorb, since this new bone is not exposed to functional (mechanical) stress. The fixation device, if left in the patient, will shield the bone defect area from functional stress and thus prevent an optimal amount of new bone formation.

SUMMARY OF THE INVENTION

The implant may be impregnated with at least one substance for cellular control. This substance for cellular control may include at least one of a chemotactic substance for influencing cell-migration, an inhibitory substance for influencing cell-migration, a mitogenic growth factor for influencing cell proliferation, a growth factor for influencing cell differentiation, and factors which promote neoangiogenesis (formation of new blood vessels). The biological tissue defect preferably comprises a bone defect and, more preferably, comprises a non-periodontal, non-oral bone defect.

The bone, which is prevented from being resorbed, may include either an autograft, an allograft, and/or new regenerated bone within the bone defect.

The implant has a thickness in a range between 100 microns and 2000 microns, but may also be configured as thin as 10 microns. This implant comprises at least one of a biodegradable synthetic material and a biodegradable natural material, that is also a non-osteogenic, non-metallic substance.

According to one aspect of the present invention, a planar membrane is provided for

resorption into the body of a patient, within a period of approximately 24 months from an initial implantation of the planar membrane into the body of the patient.

The resorbable membrane can be frictionally secured around the bone defect area, or can be secured around the bone defect area using at least one of clamps, staples, screws, sutures, and tacks. The fixation device can include at least one of a plate, a screw, an intramedullary rod, and an external fixation device.